

REMARKS

Claims 1-44 are pending for consideration.

No claims have been added, amended, or canceled. Claims 1 through 44 remain for consideration.

Claims 16-39 and 42 are allowed.

Reconsideration and allowance of the claims in light of the following remarks are respectfully requested.

35 U.S.C. §102

Claim 1 stands rejected under 35 U.S.C. §102 as being anticipated by Cawood et al. (U.S. Patent No. 4,043,328, "Cawood").

The rejection is traversed.

Claim 1 recites a medical device comprising:

a sheet . . . having an aperture . . . through which a body orifice may be accessed with a probe, wherein genitalia comprise the body orifice,

an adhesive backing operably disposed on said sheet, proximate said aperture, wherein the adhesive backing secures the sheet, proximate said aperture, to an area surrounding the genitalia . . . and

a finger cot . . .

wherein said finger cot is sized to enable access to a second body orifice.

(emphasis ours.)

Cawood fails to identically describe a medical drape having the features of claim 1, including 1) an adhesive backing proximal to an aperture that allows the drape to be secured to an area surrounding the genitalia and 2) a finger cot that enables access to a second body orifice. Thus, the rejection is untenable and should be withdrawn.

The Office action, in a "Response to Arguments," states that Cawood anticipates claim 1 because Cawood shows a medical drape having an aperture having an adhesive proximal to the aperture. This is said to anticipate claim 1 because "as to where the adhesive is used to attach the opening to the user's body is a function of the device."

However, such analysis is incomplete in that the analysis does not account for all features of claim 1. Specifically, this analysis of claim 1 in view of Cawood fails to account for features of claim 1 relating to a first aperture having adhesive proximate to said aperture through which a body orifice (of genitalia) may be accessed; and a finger cot that enables access to a second body orifice.

Applicants interpret the Response to Arguments to assert that Cawood is believed to anticipate claim 1, if adhesive surrounding an aperture of a drape of the Cawood reference could be used to secure the drape to an area surrounding genitalia. This analysis is incorrect, however, because it entirely ignores other specific features of claim 1. Even if the adhesive of the Cawood drape were placed to surround genitalia, the Cawood drape still fails to identically describe all features of claim 1. The drape does not have a finger cot to enable access to a second body orifice, which second body orifice is different from the body orifice accessed by the aperture (of genitalia) that is surrounded by adhesive.

Column 3 of the Cawood reference, starting at line 1, includes a description of how the Cawood drape and its aperture, adhesive, and “cot or sheath,” are designed for use. Adhesive surrounds a cot or sheath. The cot or sheath is described as including particular features useful for accessing a rectum and prostate, but not male or female genitalia. The cot or sheath is truly not designed to allow access to genitalia, either male or female. If, however, as proposed by the rejection, the adhesive were placed to surround genitalia, then the finger cot would be located at the genitalia. Were the drape and cot used in this manner, as proposed, it remains apparent that the Cawood drape fails to anticipate claim 1. For instance, if used as suggested, the Cawood drape does not include a finger cot for accessing a second body orifice different from the body orifice (of genitalia) accessed by the aperture surrounded by adhesive. The finger cot of Cawood would be located at the genitalia. There is no finger cot of the Cawood drape available to access a second body orifice. Therefore, all features of claim 1 are not identically met by Cawood. Accordingly, Cawood does not anticipate claim 1.

The rejection of claim 1 as anticipated by Cawood is untenable and should be withdrawn.

35 U.S.C. §103

Claims 1 and 43-44

Claims 1 and 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fenwick and Cawood, as set forth in the previous Office action, rejection of claim 1, Paper No. 7, and as further discussed in the Response to Arguments.

The obviousness rejection includes the legal conclusion that one of skill, based on the Fenwick reference combined with Cawood, would have arrived at the subject matter of claim 1. That conclusion is not supported by any convincing line of reasoning. The rejection, for example, fails to discuss all of the features of claim 1. The Response to Arguments, instead, simply states that Fenwick discloses a drape having an opening and an adhesive on the drape, and that “Cawood was used as a modifier to provide an adhesive that is proximal to the opening.” This rationale -- which fails not only to point out any specific suggestion or motivation found in either reference that would have led a skilled artisan to arrive at subject matter of claim 1, but in addition fails to even address all features of pending claim 1 -- should not be considered sufficient support for a rejection of claim as *prima facie* obvious.

An obviousness rejection requires a showing of a teaching or suggestion, within the prior art, to arrive at claimed subject matter. An obviousness rejection is to be supported by an analysis of the rejected claims and prior art, that includes: a comparison of differences between cited prior art and claimed subject matter; a proposed modification of the prior art that would have allowed one of skill to arrive at the claimed subject matter; and an explanation of why one of skill would have been motivated to make the modification. (See, e.g., MPEP 706(j)).

The rejection of claim 1 under section 103, in view of Fenwick and Cawood, is conclusory, fails to meet the requirements of a *prima facie* rejection, and does not even address all of the features of claim 1 as required. The rejection includes the following reasoning:

Fenwick discloses in the environment of a surgical drape having an opening and an adhesive on the drape. Cawood was used as a modifier to provide an adhesive that is proximal to the opening.

This basis for rejection fails. The rejection does not include any indication of how either reference would have suggested the subject matter of claim 1. In fact, the rejection fails to address the combination of features of claim 1, including:

a sheet . . . having an aperture . . . through which a body orifice may be accessed with a probe, wherein genitalia comprise the body orifice,

an adhesive backing operably disposed on said sheet, proximate said aperture, wherein the adhesive backing secures the sheet, proximate said aperture, to an area surrounding the genitalia . . . and

a finger cot . . .

wherein said finger cot is sized to enable access to a second body orifice.

This combination of features is not shown to be taught or suggested by the cited references. To the contrary, the Office action fails to include a discussion of the specific features of claim 1, in combination, or how the combination of features is suggested by the cited prior art. As a result, the rejection of claim 1 as obvious over Fenwick and Cawood is not legally supported, is untenable, and should be withdrawn.

Claims 2 through 7 and 9 through 13

Claims 2 through 7 and 9 through 13, which depend from claim 1, all stand rejected as being unpatentable over Fenwick and Cawood as applied to claim 1. The rejections of claims 2 through 7 and 9 through 13, therefore, rely on the analysis of Fenwick and Cawood as discussed in the rejection of claim 1, which, as discussed above, is not supported by the references or the analysis of the rejections of record. Specifically, the rejection of claim 1 based on Fenwick and Cawood is legally untenable. The same analysis applied to any of claims 2 through 7 and 9 through 13, as a basis of rejection, is similarly untenable, and the rejections of these claims also fail.

The rejection of these claims 2 through 7 and 9 through 13 is not legally supported, and should be withdrawn for the reasons set forth above with respect to the rejection of claim 1 based on Fenwick and Cawood.

Claims 40 and 41

Claims 40 and 41 stand rejected as being unpatentable over Fenwick and Cawood as applied to claim 1.

Independent claim 40 recites features including:

a sheet of flexible material having an aperture of a predetermined size through which a body orifice may be accessed with a probe;

an adhesive backing operably disposed on said sheet, proximate said aperture;

a finger cot disposed on said sheet; and

a pouch disposed on said sheet and sized to receive fluids discharged from the orifice,

wherein said finger cot is sized to enable access to a second body orifice with the probe . . .

The rejection is traversed for reasons discussed above with respect to claim 1, and for reasons as presented at page 14 of Applicants' Response dated March 1, 2004. As described by Applicants in earlier communications, past rejections of claim 40 (which includes subject matter of original claim 2) have been based on improper hindsight, in the absence of a requisite showing of suggestion or motivation found within cited prior art references, that would have led one of skill to arrive at the specific combination of features recited in either claim 40 or claim 41.

Overall, the present rejection is conclusory and not supported by a convincing line of reasoning. The discussion of Fenwick and Cawood as applied to claim 1, upon which the rejections of claims 40 and 41 are based, is not legally tenable. Similarly, the rejections of claims 40 and 41, said to be based on Fenwick and Cawood as applied to claim 1, are not legally tenable and should be withdrawn.

ALLOWABLE SUBJECT MATTER

Applicants acknowledge with appreciation that claims 16-39 and 42 (including subject matter of original claim 8, as re-written in independent form as of Applicants' Response dated March 1, 2004) are allowed.

The Examiner is invited to contact the undersigned, at the Examiner's convenience, should the Examiner have any questions regarding this communication or the present patent application.

Respectfully Submitted,

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